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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,032	12/06/2000	Bryan Paul Morgan	WN/KH/JJ/WCM	7516

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Young & Thompson
Second Floor
745 South 23rd Street
Arlington, VA 22202

EXAMINER	
SOUAYA, JEHANNE E	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,032	MORGAN ET AL.	
	Examiner	Art Unit	
	Jehanne E Souaya	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *03 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *1-17 and 19-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *10/2000*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Currently, claims 1-34 are pending in the instant application. Claim 18, SEQ ID NO 17, is currently under consideration at this time. Claims 1-17 and 19-34, SEQ ID NOS 18 and 19 are withdrawn from consideration as being drawn to non elected inventions. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Applicants amendment has rendered moot the rejections made under 35 USC 101, 112/2nd paragraph, and 102 in the previous office action. The following rejections are newly applied to the claim, necessitated by amendment. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Objection and Rejection

Claim Objections

3. Claim 18 is objected to because of the following informalities: the claim contains grammatical mistakes. In step c), the recitation: "said fragment encodes the first three short consensus repeats serine/threonine/proline rich region" appears to indicate that the fragment contains 3 serine/threonine/proline repeats. A thorough review of the specification, however, revealed that the three short consensus repeats, and the serine/threonine/proline rich region are separate. A comma (,) separating the different regions, would overcome the objection to the

claim. For instance, the claim could recite: "said fragment encodes the first three short consensus repeats, a serine/threonine/proline rich region (STP) and, optionally, the adjacent signal peptide" Appropriate correction is required.

Claim Rejections - 35 USC § 112

Written Description

4. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claim 18 is broadly drawn to a cDNA molecule encoding a fragment of a pig decay accelerating factor or SEQ ID NO 17, wherein the fragment encodes the first three short consensus repeats, serine threonine proline rich region and, optionally, the adjacent signal peptide. As presently worded, the claim is broadly interpreted to encompass not only cDNA fragments but also full length cDNA molecules as no length limitations are specified in the claim with regard to the recitation of 'isolated cDNA molecule" or "fragment". It is also noted that the claims are not drawn to any particular three short consensus repeats, serine threonine proline rich region, or adjoining signal peptide (that is any specific SEQ ID NO). Step a of claim 18 has no SEQ ID NO or particular structure associated with the recitation of "pig decay accelerating factor", and step c does not specifically recite that the "three short consensus repeats, serine threonine proline rich region or signal peptide are those specifically from SEQ ID NO 17 in step b. Further, the claimed cDNA molecule is broadly interpreted to encompass not only sequences

from pigs or sequences which encode decay accelerating factors, but to sequences from any source as long as they contain at least 3 short consensus repeats (the "encoding" language in the preamble is interpreted as "open" language), a serine/threonine/proline rich region, and optionally, an adjoining signal peptide.

The sequences encompassed by the amended claim recitation such as "cDNA molecule encoding", a fragment of a molecule... said fragment encodes the first three short consensus repeats, serine/threonine/proline rich region (STP) and, optionally the adjacent signal peptide" encompass mutants, variants, homologs, analogs, orthologs of SEQ ID NO: 17 or any pig decay accelerating factor, from any source. The specification does not provide adequate disclosure of sufficient embodiments to adequately describe any of the broad genera upon which the claim language reads. Even if read in the most narrow terms, the claim still reads on a very broad genus of nucleic acid molecules because the recitation of a cDNA molecule encompasses a full length cDNA molecule or fragments with only a limited structure. The recitation of any "first three short consensus repeats" any "serine threonine proline rich region" and any "adjacent signal peptide" encompass a large number cDNA sequences or partial cDNA sequences of mutants, variants, homologs, analogs, and orthologs of SEQ ID NO 17.

The specification teaches several clones of putative porcine homology to human Decay Accelerating Factor. All are taught to be identical through the signal peptide and the first three short consensus repeats (SCRs), but all diverge thereafter (page 43, lines 1 1-17). One of these clones, pDAF-7 is taught to contain 3 SCRS, a serine/threonine/proline-rich region (STP), and a carboxy-terminal sequence which may encode a glycolipid anchor or membrane anchor (page 43, lines 20-25). The specification further teaches that when the first three SCRS are fused

to Fc and expressed in Chinese Hamster Ovary cells, the fusion protein inhibits the activity of complement (Page 44, lines 6- 13). Beyond demonstrating that the first three SCR domains are sufficient to convey complement-inhibiting activity, the specification offers no teaching which correlate the sequence of pDAF-7 to its function. The specification does not teach which amino acids within the pDAF-7 protein are necessary for its function. Nor does it teach how to modify the sequence of pDAF-7 to obtain any specific homolog. It is not clear which positions within the pDAF-7 molecule can be substituted or altered without resulting in a loss of the function of the pDAF protein. Therefore, the skilled artisan would be unable to determine whether or not a DNA molecule encodes a protein that is functionally equivalent to pDAF-7 or a protein that is unrelated to pDAF-7 gene and which are unrelated DNA molecules. Although the specification does also teach the clone identified as pDAF-14, the teaching of one additional member of the genus of putative porcine Decay Accelerating Factor does not adequately describe the genus. pDAF-14 is a partial sequence and does not represent a complete open reading frame.

Enablement

5. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated cDNA molecule that encodes a polypeptide having the sequence of SEQ ID NO 17, does not reasonably provide enablement for an isolated cDNA molecule encoding a pig decay accelerating factor or a cDNA molecule encoding a fragment of a pig decay accelerating factor or a cDNA molecule encoding a fragment of a polypeptide having the sequence of SEQ ID NO 17, wherein the fragment encodes the first three short consensus repeats, serine/threonine/proline rich region (STP) and, optionally, the adjacent signal peptide. The specification does not enable any person skilled in the art to which it pertains, or with which

it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Amended claim 18 is broadly drawn to a cDNA molecule encoding a fragment of a pig decay accelerating factor or SEQ ID NO 17, wherein the fragment encodes the first three short consensus repeats, serine threonine proline rich region and, optionally, the adjacent signal peptide. As presently worded, the claim is broadly interpreted to encompass not only cDNA fragments but also full length cDNA molecules as no length limitations are specified in the claim with regard to the recitation of 'isolated cDNA molecule" or "fragment". It is also noted that the claims are not drawn to any particular three short consensus repeats, serine threonine proline rich region, or adjoining signal peptide (that is any specific SEQ ID NO). Step a of claim 18 has no SEQ ID NO or particular structure associated with the recitation of "pig decay accelerating factor", and step c does not specifically recite that the "three short consensus repeats, serine threonine proline rich region or signal peptide are those specifically from SEQ ID NO 17 in step b. Further, the claimed cDNA molecule is broadly interpreted to encompass not only sequences from pigs or sequences which encode decay accelerating factors, but to sequences from any source as long as they contain at least 3 short consensus repeats (the "encoding" language in the preamble is interpreted as "open" language), a serine/threonine/proline rich region, and optionally, an adjoining signal peptide.

The specification teaches several clones of putative porcine homology to human Decay Accelerating Factor including pDAF-7 and pDAF-14, which are taught to be identical through the signal peptide and first three short consensus repeats (SCR-S), but all diverge thereafter (page 43, lines 1 1-17). The recitation of these sequences, however, does not enable the skilled

artisan to make or identify any pig DAF cDNA. pDAF-7is taught to contain 3 SCRS, a serine/threonine/proline-rich region (STP), and a carboxy-terminal sequence which may encode a glycolipid anchor or membrane anchor (page 43, lines 20-25). Although the specification teaches that when the first three SCRS are fused to Fc and expressed in CHO cells the fusion protein inhibits the activity of complement (page 44, lines 6-13), the specification offers no guidance as to which amino acids are critical to the function of the SCR domains, or how the other identified domains function to give PDAF-7 its activity.

The specification does not teach how to modify the sequence of pDAF-7 to obtain any specific homolog. It is not clear which positions with the pDAF-7 molecule can be substituted or altered without resulting in a loss of the function of the pDAF-7 protein. Therefore, the skilled artisan would be unable to determine whether or not a DNA molecule encodes a protein that is functionally equivalent to pDAF-7 or a protein that is unrelated to pDAF-7 without undue experimentation. The sequence of pDAF-14 is also taught in the specification, however pDAF-14 is a partial sequence and does not represent a complete open reading frame. There is no sequence analysis of the domains present in pDAF-14, and no demonstrated sequence alignment of PDAF- 14 to PDAF-7. There is therefore no basis for comparison between the two sequences, and a skilled artisan would be unable to demonstrate the presence of conserved amino acid residues which might suggest a correlation between the structure and function of the PDAF clones.

A correlation between the protein of SEQ ID NO: 17 and the proteins encoded by the broad range of nucleic acid molecules recited in claim 18 is clearly unpredictable in light of the lack of guidance from the specification and the state of the art with regard to pig DAF. Since

neither the specification nor the art teach the specific amino acid residues responsible for the biological function or activity of the polypeptide of SEQ ID NO 17, for example within the SCR domains, nor how the skilled artisan could modify a specific amino acid within the polypeptide of SEQ ID NO 17 to obtain a polypeptide with either retained or modified activity, the skilled artisan would be required to perform undue experimentation to make or use the polynucleotides that encode biologically active or altered polypeptides encompassed by the broadly claimed invention.

To practice the invention as broadly as it is claimed, the skilled artisan would first have to isolate every nucleic acid encompassed by claim 18, translate these nucleic acids into polypeptides, and then determine whether or not the encoded polypeptide has activity similar to that reported for Decay Accelerating Factor. Given that the art teaches that a single amino acid change can alter the function of a biomolecule and that some of these changes are unpredictable, such analyses would require trial and error, thus constituting undue experimentation.

Claim Rejections - 35 USC § 102

6. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Liszewski et al (Annu. Rev. Immunol. Vol. 9, pp 431-455, 1991).

Amended claim 18 is broadly drawn to a cDNA molecule encoding a fragment of a pig decay accelerating factor or SEQ ID NO 17, wherein the fragment encodes the first three short consensus repeats, serine threonine proline rich region and, optionally, the adjacent signal peptide. As presently worded, the claim is broadly interpreted to encompass not only cDNA fragments but also full length cDNA molecules as no length limitations are specified in the claim

with regard to the recitation of 'isolated cDNA molecule" or "fragment". It is also noted that the claims are not drawn to any particular three short consensus repeats, serine threonine proline rich region, or adjoining signal peptide (that is any specific SEQ ID NO). Step a of claim 18 has no SEQ ID NO or particular structure associated with the recitation of "pig decay accelerating factor", and step c does not specifically recite that the "three short consensus repeats, serine threonine proline rich region or signal peptide are those specifically from SEQ ID NO 17 in step b. Further, the claimed cDNA molecule is broadly interpreted to encompass not only sequences from pigs or sequences which encode decay accelerating factors, but to sequences from any source as long as they contain at least 3 short consensus repeats (the "encoding" language in the preamble is interpreted as "open" language), a serine/threonine/proline rich region, and optionally, an adjoining signal peptide. Liszewski et al teach a cDNA molecule (figure 3) that encodes a peptide (mouse membrane cofactor protein) that contains a signal peptide, four SCRs, and a region enriched in serine, threonines, and prolines (see p. 443, legend to figure 3). Therefore, Liszewski et al anticipates the claimed invention because the molecule taught by Liszewski et al contains all of the structural requirements set forth in the claim.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Claim 18 is not allowable over the cited prior art.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Jehanne Souaya
Primary examiner
Art Unit 1634
10/14/03